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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/769,107      | 01/24/2001  | Vincent P. Sandanayaka | AM-100182 PI        | 4495             |

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EXAMINER

COVINGTON, RAYMOND K

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/769,107

Applicant(s)

Dsndsnysks et al

Examiner

Raymond Covington

Art Unit

1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 5/15/01, 6/21/01.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-52 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-52 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2, 3 20)  Other: \_\_\_\_\_

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kende et al J. Org. Chem. Vol. 55 pp.1125-1126. Kende et al teach a method of making alpha sulfone ester derivative as recited in the claims. See page 1125, scheme I and Table I.

Claims 1-52 are rejected under 35 U.S.C. 102(a) as being anticipated by Barta et al WO 00/71514. Barta et al teach sulfonyl hydroxamic acid derivative as recited in the claims. See page 8, lines 10-page 13, line 22 for example.

Claims 1-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for  $R_1$ ,  $R_2$  piperidine derivative does not reasonably provide enablement for derivatives drawn to the cast range of heterocyclic containing derivatives, particularly, for example thio morpholine derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. There is insufficient enabling disclosure to support the terms heteroaryl, cycloheteroalkyl.

Claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The specification does not give any guidance as to how each of the heterocyclic substituted derivatives was prepared. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, applicants are claiming heterocyclic substituted alkylene diamine derivatives. Applicants have not disclosed any working examples, which would demonstrate, or guide, one skilled in the art as to how the heterocyclic substituted derivatives other than R<sub>1</sub>R<sub>2</sub> piperidine derivatives, were prepared or obtained. The process of making the heterocyclic substituted derivatives or how the heterocyclic substituted derivatives were obtained is not readily apparent from the specification. The specification must teach how to make the invention. *In re Gardner*, 166 U.S.P.Q. 138 (1970). In order to practice the claimed invention, one skilled in the art would have to

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Speculate how derivatives were obtained or prepared. Therefore, the instant invention is not enabled. Claims limiting the scope of these should overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703)308-4704. The Examiner can normally be reached on Monday-Friday 9 am- 3pm.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Alan Rotman can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-308-4556 for After Final communications.

*mv*  
Covington:mv  
March 13, 2002

*Alan L. Rotman*  
ALAN L. ROTMAN  
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